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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,957	06/20/2003	Garth Powis	126387.530	6628

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Pepper Hamilton LLP
One Mellon Center, 50th Floor
500 Grant Street
Pittsburgh, PA 15219

EXAMINER

FETTEROLF, BRANDON J

ART UNIT	PAPER NUMBER
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1642

MAIL DATE	DELIVERY MODE
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01/22/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/600,957	Applicant(s) POWIS, GARTH	
	Examiner Brandon J. Fetterolf, PhD	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2007 has been entered.

Claims 7-18 are currently pending and under consideration.

Rejection Withdrawn:

The provisional rejection of Claims 7-8 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 5 and 7 of copending Application No. 10/617,949 is withdrawn in view of the filing and approval of the terminal disclaimer.

The rejection of Claims 7-10 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, THIS IS A NEW MATTER REJECTION, is withdrawn in view of Applicants amendments..

Rejections Maintained:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-10 remain rejected and new claims 11-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Oblong et al. (Cancer Chemotherapy and Pharmacology 1994; 34: 434-438, *IDS*) as evidenced by Ashburn (US 20070010543, 2007, of record).

Oblong et al. teach a composition comprising an agent in DMSO, wherein the agent acts as a reversible inhibitor of human thioredoxin (page 435, 1st column, *TR assay*, page 436, 1st column, 1st

full paragraph and Title). With regards to the thioredoxin inhibitor, the reference teaches that the thioredoxin inhibitors are alkyl 2-imidazole disulfide analogues, such as 1-methylpropyl-2-imidazolyl disulfide (Title and page 435, 1st column, *Chemicals* and Fig. 1). Moreover, the reference teaches that the alkyl 2-imidazolyl disulfide analogues are useful at inhibiting cellular proliferation, e.g. cell growth (page 437, Fig. 4A,B and 2nd column, last paragraph). Thus, while Oblong et al. do not explicitly teach that the agent is useful in reducing or eliminating thioredoxin-associated apoptosis inhibition, the intended use of the compound must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A composition is a composition irrespective of what its intended use is. See In re Tuominen, 213 USPQ 89 (CCPA 1982). Secondly, although Oblong et al. does not explicitly teach that DMSO is an acceptable carrier, the claimed limitation does not appear to result in a manipulative difference when compared to the prior arts disclosure because as evidenced by Ashburn, DMSO is an example of an acceptable carrier (paragraph 0049). Thus the claimed composition appears to be the same as the prior art.

In response to this rejection, Applicants assert that Oblong describes 1-methylpropyl-2-imidazolyl disulfide among a number of asymmetric disulfides. However, Applicants assert that not until the present application that 1-methylpropyl-2-imidazolyl disulfide is a drug because it inhibits thioredoxin, as opposed to thioredoxin reductase. In addition, Applicants contend that they unexpectedly found that certain 2-imidazolyl disulfides irreversibly bind to Cys73 of thioredoxin and block its reduction by thioredoxin reductase. Further, Applicants contend that this unexpected discovery provides one with the ability of determining an effective amount of 2-imidazolyl disulfide in order to reduce or eliminate thioredoxin-associated apoptosis inhibition or inhibit thioredoxin stimulated apoptosis. In particular, Applicants contend that Oblong failed to appreciate that 2-imidazolyl irreversibly bind to Cys73 of thioredoxin, and therefore fails to teach that 1-methylpropyl-2-imidazolyl disulfides as a drug that would be useful for reducing or eliminating thioredoxin-associated apoptosis inhibition or inhibiting thioredoxin stimulated cell growth. As such, Applicants contend that Oblong fails to anticipate claims of the present invention, and this rejection should be withdrawn.

These arguments have been carefully considered, but are not found persuasive.

First, as noted above, the Examiner recognizes that the claims are drawn to a product, e.g., a drug comprising a 2-imidazolyl disulfide and an acceptable carrier, and while Oblong et al. do not explicitly teach that the agent is useful in reducing or eliminating thioredoxin-associated apoptosis inhibition, inhibits tumor growth, inhibits thioredoxin or irreversibly binds to thioredoxin or the Cys73 of thioredoxin, the intended use of the compound must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A composition is a composition irrespective of what its intended use is. See In re Tuominen, 213 USPQ 89 (CCPA 1982). Moreover, while the Examiner acknowledges and does not dispute Applicants assertions that they unexpectedly found that certain 2-imidazolyl disulfides irreversibly bind to Cys73 of thioredoxin and block its reduction by thioredoxin reductase, the Examiner recognizes that it does not appear that Applicants have provided a patentable difference between the composition comprising 1-methylpropyl-2-imidazolyl disulfide and DMSO taught by the prior art and the instantly claimed composition or drug comprising 1-methylpropyl-2-imidazolyl disulfide and an acceptable carrier.. In the instant case, “[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer.” *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979).

Therefore, No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

Application/Control Number:
10/600,957
Art Unit: 1642

Page 5

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon J Fetterolf, PhD
Patent Examiner
Art Unit 1642



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